Citation:

Smith RE, Kok A, Rothberg AD, Groeneveld HT. Determinants of blood pressure in Sowetan infants. *S Afr Med J.* 1995 Dec; 85(12 Pt 2): 1,339-1,342.

PubMed ID: 8600606

Study Design:

Prospective cohort

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEGATIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the association between early salt intake and blood pressure (BP) in Sowetan infants, and secondarily to examine the association between anthropometric measurements and familial influences on infant BP.

Inclusion Criteria:

Sowetan infants enrolled in the Birth-to-Ten cohort study, which includes all children born between April 23 and June 8, 1990 in Johannesburg and Soweto, South Africa.

Exclusion Criteria:

Infants who did not have complete data sets on variables of interest.

Description of Study Protocol:

Recruitment

Pregnant women were recruited to participate in the Birth-to-Ten cohort study.

Design

Prospective cohort with a one-year follow-up of infants.

Dietary Intake/Dietary Assessment Methodology

A comprehensive feeding history was obtained from the mother of each infant and details pertinent to salt intake were assessed.

Statistical Analysis

- Multivariate analysis was used to investigate the association between BP and selected variables
- Pairwise T-tests and tests of linear correlation were also used.

Data Collection Summary:

Timing of Measurements

- Background information was obtained by questionnaire prior to the birth of the infant
- Blood pressure, salt intake and other variables were measured at one year of age.

Dependent Variables

Blood pressure.

Independent Variables

Salt intake was measured by administering a questionnaire to the mother on feeding practices.

Control Variables

- Weight, length, skull circumference, upper arm circumference, triceps and subscapular skinfold thickness
- Gender, breast-fed or not, age of weaning, age at which formula was started, volume of formula per 24 hours, salt concentration formula, month in which salts were introduced and amount of salt added to diet per day
- History of hypertension (HTN) in the infants' mothers.

Description of Actual Data Sample:

- *Initial N:* More than 2,500
- *Attrition (final N):* 684 (353 for maternal influence on infants' BP)
- *Age:* One year
- *Anthropometrics:* Infants were generally lighter and shorter than the norms for age
- *Location:* Johannesburg and Soweto, South Africa.

Summary of Results:

Other Findings

- After adjusting for covariates, there was an NS trend toward a dose-related response between salt intake and BP, with a positive linear relationship between BP and quantity of salt added (up to half a teaspoonful)
- In multiple linear regression analysis, 29.3% of the variance for systolic blood pressure at one year of age could be attributed to the following factors: Weight (P=0.0001), upper arm circumference (P=0.0007), formula start (P=0.0096), length (P=0.0346) and volume (P=0.0598). Added salt approached significance (P=0.0751)
- There was a weak, but significant correlation between history of maternal BP and infants' BP (R=0.1072, P=0.0249).

Author Conclusion:

Given the limitations of the study, no firm claims can be made about the association between salt intake and BP in infants.

Reviewer Comments:

- *Author-identified limitations:*
  - *The contribution of upper arm circumference to the variance in BP may be a consequence of incorrect cuff size*
  - *Staff were also trained to collect data at six months and two years, but these data were unreliable and incomplete*
- *Another limitation is potentially inaccurate dietary sodium intake measurements. A retrospective questionnaire was administered to infants' mothers to obtain dietary salt intake measurements by feeding practices over the first year of life. Thus, there was a lack of actual measurement of dietary sodium intake by the infant subjects*

- *Study strength: Multivariate analysis was used to adjust for potential confounders.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	N/A

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	???

2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	No
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	N/A
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	???
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	???
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No

5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	No
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	???
7.5.	Was the measurement of effect at an appropriate level of precision?	No
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes

	7.7.	Were the measurements conducted consistently across groups?	???
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	No
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		???
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	???